Submitted electronically to: Bipartisan340BRFI@email.senate.gov

March 28, 2024

Senator Shelley Moore Capito (R-WV)
Senator John Thune (R-SD)
Senator Debbie Stabenow (D-MI)
Senator Tammy Baldwin (D-WI)
Senator Jerry Moran (R-KS)
Senator Ben Cardin (D-MD)

Re: Bipartisan 340B Senate Working Group SUSTAIN 340B Act Discussion Draft, Explanatory Statement and Supplemental RFI

Senators Capito, Thune, Stabenow, Baldwin, Moran, and Cardin:

The National Community Pharmacists Association (NCPA) appreciates the opportunity to provide comments to the Bipartisan 340B Senate Working Group on its *SUSTAIN 340B Act* Discussion Draft, Explanatory Statement and Supplemental RFI.

NCPA represents America's community pharmacists, including 19,400 independent community pharmacies. Almost half of all community pharmacies provide long-term care services and play a critical role in ensuring patients have immediate access to medications in both community and long-term care (LTC) settings. Together, our members represent a $94 billion healthcare marketplace, employ 230,000 individuals, and provide an expanding set of healthcare services to millions of patients every day. Our members are small business owners who are among America's most accessible healthcare providers. NCPA's answers to select questions of the Senate RFI are below. Excerpts from the Senate RFI and Discussion Draft are provided in quoted, italicized text.

SECTION 3. Contract Pharmacy

"Many community health centers and hospitals in rural and underserved areas see patients from large service areas, many of whom have limited transportation options. Many of these health centers and hospitals do not have an in-house pharmacy and thus rely on contract pharmacy arrangements to provide patients access to medications. How would you structure any geographic restriction or other restriction on contract pharmacies to ensure patients in rural and underserved areas maintain access to drugs?"

NCPA supports a geographic restriction that the contract pharmacy must be within 150 miles of their covered entity for rural census areas, and within 75 miles for urban populations. Most NCPA members who participate in the 340B program do so within a 75-mile radius of their contracting entity, but advocate for the 150 mile/75 mile limit due to concerns about potentially limiting access to specialty drugs if the geographic restrictions were tighter. NCPA also advocates

for this 150 mile/75 mile restriction to protect beneficiary access to community pharmacies. Additionally, such a geographic restriction would limit abuses of mail-order pharmacies shipping large quantities of 340B drugs outside of the communities of the contract entities.

"We have heard concerns from stakeholders about the number of contract pharmacies used by covered entities in the program. However, we also understand that not all of these pharmacies may be actively providing prescriptions to patients as part of the 340B program and are only included due to other contractual requirements, such as effectively requiring them to contract with an entire pharmacy chain, regardless of their need or preference. What policies would allow covered entities to contract with pharmacies to ensure patients have access, without additional requirements or limitations? What policies should be implemented to limit the role of PBMs' influence in the 340B program and ensure the benefits of the 340B program remain with the covered entities and eligible patients?"

To promote beneficiary access to the pharmacies of their choice, NCPA opposes arbitrary manufacturer restrictions on the 340B program.[1]

PBMs and insurers should be prohibited from discriminating against health providers participating in the 340B drug pricing program, including pharmacies contracted with such providers to dispense 340B drugs. PBMs and insurers should be prohibited from engaging in discriminatory pricing, where PBMs and insurers pay prescription claims at different rates when the pharmacy identifies a claim as 340B.[2] Such discriminatory pricing causes covered entities and contract pharmacies to carve out claims, which in turn restricts patient access.

PBMs should also be prohibited from pickpocketing profits from 340B, through spread pricing or other opaque reimbursement systems.

Specifically, NCPA believes that the Working Group should add the following to the bill language:

PBMs and insurance plans should not be allowed to:

- **Reimburse 340B participants at a lower rate than other entities not participating in the program;**
- **Impose differing terms (such as fees, charge-backs, or audits) on 340B participants;**
- **Interfere with an individual's choice to receive drugs from a 340B participant;**
- **Require 340B participants to identify which drugs fall within the program;**
- **Refuse to contract with a 340B participant on the basis that they utilize the program;**

[1] For a compilation of such restrictions, see https://www.amerisourcebergen.com/provider-solutions/340b-advisory-services/340b-manufacturer-updates.

[2] See https://rwc340b.org/dc-circuit-rules-on-340b-medicare-advantage-discriminatory-reimbursement-case/ for more information.

- **Arbitrarily re-classify pharmacies as ineligible to provide 340B if they cannot submit N1 transactions, or for other reasons; or**
- **Deny coverage of drug because it is a 340B drug.**

Further, NCPA argues that the Committee should also place language in this bill that makes clear that any state penalties, remedies, and enforcement protections currently in place against PBMs and insurers from abusing the 340B program would not be preempted by the SUSTAIN 340B Act.

Audits. Section 3 contains language that subjects the contract pharmacy to audits by the covered entity, as well as the Secretary. **NCPA supports contract pharmacies supporting covered entities in their audit requirements, and suggests that this Working Group consider audits on TPAs and PBMs in how they process 340B claims.**

Customary business practices. Section 3 contains language that "the contract pharmacy will provide the covered entity with any information requested consistent with customary business practices, such as quarterly billing statements, status reports of collections, and receiving and dispensing records." **NCPA opposes this language, including but not limited to "any information requested consistent with customary business practices" as it is overly broad and puts contract pharmacy at great risk of abusive audits from covered entities.**

Standard contract provisions. Section 3 also contains language that allows the Secretary to promulgate rules to ensure the integrity of contract pharmacy arrangements, including to prevent diversion and duplicate discounts, including developing standard contract provisions that are required to be included in written agreements between contract entities and pharmacies. These standard contract provisions include provisions providing that the covered entity and the contract pharmacy will develop and implement a system to verify eligibility of patients, and maintain safeguards to prevent diversion of covered outpatient drugs purchased under this section to individuals who are not patients of the covered entity.

Given the infeasibility of pharmacies identifying 340B claims (see our comments to Section 8 below), NCPA opposes standard contract provisions including language preventing duplicate discounts. Additionally, NCPA opposes standard contract provisions that require pharmacies to develop and implement a system to verify the eligibility of patients, which is the responsibility of the covered entity and the third-party administrator, not the contract pharmacy.

Registration of contracts. Section 3 contains language requiring covered entities to annually register with the Secretary their contracts with their contract pharmacies. **NCPA opposes this provision.** NCPA is concerned that unredacted contracts may fall into the hands of PBMs, who would then have anti-competitive access to pharmacy reimbursement and cost of dispensing information. NCPA is also concerned that the Secretary will also use this information to mandate cost structure and reimbursement of contract pharmacy in the 340B program, and not properly

consider the variable nature of contracts given urban/rural areas and the number of competing contracts in the area.

SECTION 4: Patient Definition

"The 340B statute does not include a definition of patient. In 1996, HRSA proposed a patient definition and then proposed a revised definition in 2015 which they then withdrew. Since the program has evolved since the original statute was written, how should these changes be reflected in how a patient is defined?"

NCPA supports the original 1996 patient definition as proposed by HRSA:

> **(C) Definition of a Patient**
> An individual is a ''patient'' of a covered entity (with the exception of State-operated or funded AIDS drug purchasing assistance programs) only if:
>
> 1. the covered entity has established a relationship with the individual, such that the covered entity maintains records of the individual's health care; and
>
> 2. the individual receives health care services from a health care professional who is either employed by the covered entity or provides health care under contractual or other arrangements (e.g. referral for consultation) such that responsibility for the care provided remains with the covered entity; and
>
> 3. the individual receives a health care service or range of services from the covered entity which is consistent with the service or range of services for which grant funding or Federally-qualified health center look-alike status has been provided to the entity. Disproportionate share hospitals are exempt from this requirement.
>
> An individual will not be considered a ''patient'' of the entity for purposes of 340B if the only health care service received by the individual from the covered entity is the dispensing of a drug or drugs for subsequent self-administration or administration in the home setting.
>
> An individual registered in a State operated or funded AIDS drug purchasing assistance program receiving financial assistance under title XXVI of the PHS Act will be considered a ''patient'' of the covered entity for purposes of this definition if so registered as eligible by the State program.

Additionally, NCPA supports the ruling of the *Genesis Health Care Inc. v. Health Resources and Services Administration* decision, which held that:

- An individual only needs to be a patient of the covered entity for purposes of 340B eligibility;

- The plain wording of the 340B statute does not require the covered entity to have initiated the health care service resulting in the prescription;
- Agency interpretations in contradiction of the plain wording of a statute are not entitled to deference and are not enforceable; and
- While HRSA has the authority to implement its interpretations of the statutory term "patient" in the 340B statute, its interpretation of "patient of the entity" in the 340B statute meaning that the covered entity must have "initiated the healthcare services resulting in the prescription" was contrary to the statute.

NCPA supports the *Genesis* decision, which by rejecting HRSA's more restrictive interpretation of "patient," leaves open the possibility that 340B-covered entities can qualify as 340B eligible prescriptions written by prescribers that are unaffiliated with the 340B-covered entity and not under "referral" arrangements as contemplated by the 1996 guidance.

NCPA does not support the narrower restrictions of patient definition as proposed by HRSA in the 2015 revisions, specifically the language "Under this proposed guidance, an individual will be considered a patient of a covered entity, on a prescription-by-prescription or order-by-order basis…"

SECTION 7: Enhancing Program Integrity

"This section authorizes the Secretary to perform audits on covered entities, child sites, contract pharmacies, and manufacturers to ensure compliance under the statute."

NCPA advises the Working Group that it is the covered entities, not the contract pharmacies, which are responsible to HRSA to make sure that prescriptions qualify for the 340B program. The TPAs role is to identify eligible claims for the 340B program. **Given this and our concerns with PBMs' role in the 340B program, NCPA suggests that this Working Group consider audits on TPAs and PBMs in how they process 340B claims.**

"Covered entities must extend their patient financial assistance policies to patients served at their child sites and contract pharmacies. The covered entity must ensure the financial assistance option is made transparent to patients and publicly reported."

NCPA believes that any patient financial assistance policies that patients receive from the covered entities should be limited in scope to the covered entity's criteria for financial assistance. Further, NCPA maintains that any education and provision of documentation regarding patient financial assistance policies be the responsibility of the covered entity, not the contract pharmacy, due to the significant administrative burden on pharmacy that this would otherwise cause.

SECTION 8: Preventing Duplicate Discounts

In the summary of the Discussion Draft, the Senators stipulate that the Secretary must enter into a contract with an independent, third-party entity to carry out the duties of a national clearinghouse to prevent duplicate discounts between the 340B program and Medicaid; the

national clearinghouse must perform the duties laid out in this section, including requesting and receiving claims level rebate file data from State Medicaid agencies and covered entities and maintaining the data in a confidential manner; and covered entities must participate in the data exchange with the third-party clearinghouse, including available data from contract pharmacies.

According to the draft bill text, the clearinghouse can:

> "(1) request and receive, in the most efficient and least burdensome manner practicable—
> ''(A) claims level rebate file data under 23 section 1927, from State Medicaid agencies;
> ''(B) claims level data from covered entities; and
> ''(C) any other data specified by the Secretary as necessary for the entity to carry out this section;[…]"
> "(2) request, receive, and maintain data described in paragraph (1) in a confidential manner;
> "(3) ensure that claims-level data submissions by covered entities are complete and accurate, and if not, obtain complete and accurate data from the covered entity;
> "(4) notify the covered entity, the Secretary, the State Medicaid agency, and the manufacturer of any violation described in paragraph (2) to allow for remediation;
> "(5) provide the manufacturer of a 340B drug with claims-level data submitted by a covered entity, so that the manufacturer may identify units of a 340B drug that may generate a rebate or discount under a voluntary rebate or discount arrangement, such as those related to commercial plans;
> "(6) where feasible, share with a covered entity, the Secretary, a Medicaid State agency, or a manufacturer, data the third-party entity identifies in a timely manner with the purpose of preventing any of the violations described in section 2729A(b)(2) of the Public Health Service Act;

Regarding 1(C) above (language that the clearinghouse can request and receive "any other data specified by the Secretary as necessary for the entity to carry out this section," NCPA has reservations of what kind of additional data State Medicaid agencies and the covered entities are getting from contract pharmacies under this draft bill, and if this data in turn could be used by manufacturers for nefarious purposes.

Regarding the stipulation that covered entities must participate in the data exchange with the third-party clearinghouse, including available data from contract pharmacies, NCPA re-iterates the infeasibility of pharmacies identifying 340B claims, either proactively or retroactively. NCPA has found that the N1 transaction is not feasible as it is not adopted by pharmacy information systems. For NCPA's full comments on this matter, see our March 2023 feedback on *CMS' Medicare Part D Drug Inflation Rebates Paid by Manufacturers: Initial Memorandum, Implementation of Section 1860D-14B of Social Security Act, and Solicitation of Comments*.

NCPA requests that the clearinghouse not provide the drug manufacturer with the claims-level data. First, allowing the clearinghouse to provide the drug manufacturer with claims-level data would compromise patient confidentiality. Second, drug companies may use the claims-level data for impermissible purposes, like making their own 340B eligibility determinations and denying 340B prices if they determine that a covered entity does not meet the companies' inevitably restrictive eligibility criteria. Third, drug companies may use the data to obtain market advantages. **Rather, NCPA believes the clearinghouse should have a process to de-duplicate the State's rebate files after comparing them to the covered entities' 340B claims data – submitted via a flat file.** States would use the de-duplicated claims data to make their rebate request to drug companies. This model is similar to the Oregon model, and has the virtue of not requiring covered entities or their contract pharmacies to add burdensome modifiers.

SECTION 9. Ensuring Equitable Treatment of Covered Entities and Participating Pharmacies

NCPA supports the language proposed that ensures plans and PBMs cannot place differential terms on covered entities or their contract pharmacies. For example, NCPA supports:

- Language prohibiting a group health plan, a health insurance issuer offering group or individual insurance coverage, or a pharmacy benefit manager from discriminating against covered entities, contract pharmacies, or other participants in the 340B program.
- Language specifically prohibiting lower reimbursement rates for covered entities and contract pharmacies participating in 340B, refusal to contract with a covered entity or contract pharmacy, or interfering with an individual's choice to receive a 340B drug.
- Language prohibiting health plans and pharmacy benefit managers from imposing terms and conditions on covered entities and contract pharmacies that differ from other terms and conditions applied to similarly situated entities, such as chargebacks, clawbacks, or other fees.
- Authorizing the Secretary to impose civil monetary penalties on any pharmacy benefit manager that violates these requirements.

SECTION 10. User Fee Program

NCPA maintains that, while the Senators' language stipulates that covered entities participating in the 340B program pay user fees, contract pharmacies should not be paying user fees.

SECTION 11. Studies and Reports

NCPA opposes the language requiring HHS to conduct a study on dispensing fees and to submit the study to Congress two years after the date of enactment, for purposes of establishing reasonable dispensing fees associated with contract pharmacies. NCPA proposes that the dispensing fee and any other reimbursement be negotiated between the covered entity and contract pharmacy based on the specifics of their arrangement, therefore negating the need for a dispensing fee study.

NCPA thanks the Senators for the opportunity to comment. Should you have any questions or concerns, please feel free to contact me at anne.cassity@ncpa.org or (703) 838-2682.

Sincerely,

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National Community Pharmacists Association